

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 16097	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP03/12931	International filing date (day/month/year) 9 October 2003 (09.10.2003)	Priority date (day/month/year) 9 October 2002 (09.10.2002)
International Patent Classification (IPC) or national classification and IPC  Int. Cl <sup>7</sup> G01N1/10		
Applicant  SUNSTAR INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of \_\_\_\_\_ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement;
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 21 April 2004 (21. 04. 2004)	Date of completion of this report 12 January 2005 (12. 01. 2005)
Name and mailing address of the IPEA/JP Japanese Patent Office, 4-3, Kasumigaseki 3-chome Chiyoda-ku, Tokyo 100-8915, Japan	Authorized officer
Facsimile No.	Telephone No. (81-3) 3581-1101

**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☒ the international application as originally filed.
- ☐ the description:  
pages \_\_\_\_\_, as originally filed.  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the claims:  
pages \_\_\_\_\_, as originally filed.  
pages \_\_\_\_\_, as amended (together with any statement under Article 19  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the drawings:  
pages \_\_\_\_\_, as originally filed.  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
pages \_\_\_\_\_, as originally filed.  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b))
- ☐ the language of publication of the international application (under Rule 48.3(b))
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3)

**3. With regard to any nucleotide and /or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ Furnished subsequently to this Authority in written form.
- ☐ Furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

**4. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17)

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	1-22	YES
	Claims		NO
Inventive step(IS)	Claims	8-10, 18, 19	YES
	Claims	1-7, 11-17, 20-22	NO
Industrial applicability(IA)	Claims	1-22	YES
	Claims		NO

**2. Citations and explanations**

Document 1 [JP 5-187976A (SALIVA DIAGNOSTIC SYSTEMS INCORPORATED), 1993.07.27, full text, all figures] describes a sputum-collecting tool comprising a sputum collector with a base portion having a handle portion at the other end, and a collection sample container for holding said sputum collector.

Document 2 [US 3776220 A (Frank Monaghan), 1973.12.04, full text, all figures] describes a sample-collecting tool wherein grip faces of a handle portion are formed substantially flat, and a left/right width dimension of said handle portion is set larger than a left/right width dimension of a base portion so as to hold the handle portion by frictional force.

Document 3 [JP 8-285845 A (Wako Pure Chemical Industries, Ltd.), 1996.11.01, paragraph [0 0 1 7], [Fig. 1], and [Fig. 5]] describes a sample-collecting tool having an extraction stripe at one end which constitutes a projection protruding externally and is detached so that inner reserving liquid can be extracted.

Document 4 [JP 8-502670 A (Epitope, Inc.), 1996.03.26, page 9, lines 12 - 17, all figures] describes a sputum-collecting tool wherein a sputum-collecting portion is made of polyurethane.

Document 5 [JP 10-96725 A (Hisamitsu Pharmaceutical Co., Inc.), 1998.04.14, paragraphs [0 0 0 1], [0 0 1 8], and [0 0 1 9]] describes a sputum-examination device having a sheet stripe consisting of cellulose acetate, said sheet stripe being with a mobile label composition.

Document 6 [JP 2001-33359 A (Soichi Nakagawa), 2001.02.09, full text, all figures] describes an envelope for sending a sample container by mail.

Document 7 [JP 2001-264310 A (TAIHO INDUSTRIES CO., LTD.), 2001.09.26, full text, all figures] describes a test kit comprising a casing body to hold a sample container, and a lid.

Document 8 [CD-ROM which recorded specification and figures which are attached to the written application of Japanese Utility model application No. 5-69780 (Laid-Open No. 7-41462), (DAINIPPON INK AND CHEMICALS, INC.), 1995.07.21, full text, all figures] describes a packaging body for a sample-collecting container having a retaining portion to retain the sample-collecting container in upstanding position.

Document 9 [JP 3083805 U (SEKISE, Inc.), 2001.11.21] describes a sample-collecting kit with instructions.

**Claim 1**

It is easy for the skilled in the art to employ a handle portion of a sample-collecting tool which is described in the cited document 2 for a sputum-collecting tool which is described in the cited document 1.

**Claim 2**

A handle portion of a sample-collecting tool which is described in the cited document 2 (col. 2, lines 7-10) has a bumpy portion for causing frictional force.

## Supplemental Box

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## Claim 3

An upper side portion 10 of a sample-collecting tool which is described in the cited document 2 has a bulge so as to prevent fingers grasping a handle portion 12 from moving to a base portion side. Said "bulge" corresponds to the "stopper portion" of the invention concerning to Claim 3.

## Claim 4

A sputum-collecting portion (filter paper) which is described in the cited document 1 (cf. [ 0 0 2 4 ]) contains colorants which can be dispersible by sputum.

## Claim 5

It is easy for the skilled in the art to employ a handle portion of a sample-collecting tool which is described in the cited document 2 and an extractable extraction stripe which is described in the cited document 3 for a sputum-collecting tool which is described in the cited document 1.

## Claim 6

The invention which is described in the cited document 1 (Fig. 18) has a flange portion between a handle portion and a sputum-collecting portion.

## Claim 7

Whether or not to compose a handle portion so as to be covered at least part by a sample-collecting container in the invention which is described in the cited document 1 is a matter to be appropriately designed by the skilled in the art.

## Claim 11

A sputum-collecting tool which is described in the cited document 4 has a sputum-collecting portion of polyurethane.

## Claim 12

A sputum-collecting tool which is described in the cited document 5 has a sputum-collecting portion of cellulose acetate.

## Claim 13

The diameter of a sample container which is described in the cited document 6 is 10 mm or less so as to be sent by mail. The diameter of the sample container is a matter that the skilled in the art can appropriately design.

## Claim 14

The cited document 7 describes a testing kit. To make a sample-collecting tool into a kit is a matter that the skilled in the art can appropriately attain.

## Claim 15

The cited document 8 describes a packaging body of a sample-collecting container having a retaining portion to retain the sample-collecting container in the upstanding position.

## Claim 16

The cited document 9 describes instructions of a sample-collecting kit. To attach instructions to the kit is a matter that the skilled in the art can appropriately attain.

## Claim 17

The cited document 6 describes an envelope to send a sample container by mail. To include an envelope in components of a sample-collecting kit is a matter that the skilled in the art can appropriately attain.

## Claims 20 to 22

The reason is similar to the reasons for Claims 11 to 13.